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10/692,063

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David F. Davenport

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EXAMINER

ARNOLD, ERNST V

ART UNIT

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1616

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/692,063	<b>Applicant(s)</b> DAVENPORT ET AL.	
	<b>Examiner</b> ERNST V. ARNOLD	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 1/20/10.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-38,40-48 and 50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-38,40-48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/20/10 has been entered.

Claims 25-38, 40-48 and 50 are pending and under examination.

#### **Withdrawn rejections:**

Applicant's amendments and arguments filed 1/20/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 25, 26, 33, 38, 40-42, 44, 46, and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (US 4522832). Claims 25-38, 40-48, and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (US 5902797) in view of Martinez et al. (J Dairy Sci. 1998, 71, 893-900) and The Merck manual of medical information Home Edition Robert Berkow Ed. Published by Merck Research Laboratories Whitehouse Station, NJ 1997, pages 535-536 and Mahmoud et al. (US 5,104,676) and Hsia (US 6,294,166) and Acosta et al. (US 5550146). These rejections are withdrawn in favor of the rejections to follow.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-38, 40-48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25 and 50 introduce new matter as the claims recite the limitation: "digestive tract condition" There is no support in the specification for this limitation. The limitation of: "digestive tract condition" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses "digestive tract disease" in [00093] but does not describe the instantly claimed limitation. There is no guidance in the specification to select "digestive tract condition" because this is a broadening of the scope. A 'digestive tract condition' can be the state of the digestive tract which can be good or poor or bad or limited whereas a digestive tract disease is defining a particular state of the digestive tract. From MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure

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does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claims 25-38 and 40-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 25 introduces new matter as the claim recites the limitation: "less than about 100" There is no support in the specification for this limitation. The limitation of: "less than about 100" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses "about 100" in original claim 39 but does not describe the instantly claimed limitation. There is no guidance in the specification to select "less than about" and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 25-38 and 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase 'less than about' is indefinite. Either the value is 'less than' which is static or the value is 'about' which is dynamic. The value cannot simultaneously be static and dynamic.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Lewis, Lon (Feeding and Care of the Horse second edition; 1995, Blackwell Publishing Professional, Ames, Iowa).

Lewis discloses that horses with **liver disease**, which reads on hepatic dysfunction, should be **tube fed**, hence enterally, with a diet that **meets energy needs**, hence is energy promoting and reduces the energy deficit, protein needs, and be low in or not contain fat (page 296, left column). A composition with no fat is less than 3% fat. The composition has an effective proportion of components in the absence of evidence to the contrary. Thus, Lewis fairly discloses a method of tube feeding a horse with hepatic dysfunction with a diet containing no fat and that meets energy needs and is thus in effective proportions. Claim 50 is anticipated.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-38, 40-48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Lon (Feeding and Care of the Horse second edition; 1995, Blackwell Publishing Professional, Ames, Iowa) and Lewis, Lon (Equine Clinical Nutrition Feeding and Care; 1995, Williams & Wilkins, Media, Pa) and Parsons, HS., (Care and Management of the Older Horse; 2001, Trafalgar Square Publishing, North Pomfret, Vermont) and Weese et al. (Abstract; J. Am Vet. Med. Assoc 1999, 214(2), 229-32).

Applicant claims:

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25. (currently amended) A method for reducing energy deficit in a mammal with an energy deficiency due to hepatic dysfunction, renal dysfunction, or digestive tract condition, comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components;

wherein the composition comprises a protein component comprising whey powder and lactase in the following approximate effective proportions: between about 95% ~~to~~ and less than about 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase.

### Determination of the scope and content of the prior art

#### (MPEP 2141.01)

In the feeding and care of the horse, Lewis provides chapters on Energy (chapter 1), Minerals (chapter 2), Vitamins (chapter 3), Harvested Feeds (chapter 4), Diet evaluation (Chapter 6), Horse Feeding Practice (chapter 8) and Feeding and Care of Horses with Health Problems (chapter 17) (page 4 of 14). Lewis teaches whey, which is what remains after milk proteins have been removed following drying, still contains 17-18% protein but is primarily lactose and is a source of protein for horses (page 88). It is the Examiner's position that dried **whey is a powder** in the absence of evidence to the contrary. Lewis teaches that horses over 3 years of age have little lactase which can be a problem for older horses who consume enough lactose to cause diarrhea (page 88). Lewis teaches that common horse feeds contain 2-6% fat (page 18, right column). Thus feed supplements of 2% fat are known. Lewis teaches feeding and care of horses with health problems including **diarrhea** (a digestive tract condition) liver disease



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(hepatic dysfunction) and kidney failure (renal dysfunction) (chapter 17 title page). **Thus, all of the instant disorders are covered in Lewis.** Horses with **liver disease**, which reads on hepatic dysfunction, should be **tube fed**, hence enterally, with a diet that **meets energy needs, protein needs**, and be low in or not contain fat (page 296, left column). Lewis teaches that in **renal failure** a vitamin supplement is recommended to be added to the diet (page 296 Kidney Failure). Harvested feeds for horses include oats, **hay**, brewer's yeast, dried milk products, probiotics and bioflavonoids (chapter 4 title page). Vitamins include vitamins, A B1, B2, C, D, E, K, niacin, pantothenic acid, pyridoxine, biotin, floccain, cobalamin, and choline (chapter 3, title page). The composition has an effective proportion of components in the absence of evidence to the contrary. (Please note that the Examiner only had a limited preview of this book on Google books and could not access all the pages at this time.)

In equine clinical nutrition, Lewis (*the same author of the feeding and care of the horse above*) teaches that alfalfa is hay (page 16, right column). Lewis teaches that proteins are composed of **22 different amino acids** and feeds provide a sufficient amount of each amino acid (page 16, left column). Lewis teaches **minerals** for horses including sodium chloride salt, calcium, molybdenum, potassium, iron, copper, iodine, selenium, manganese and magnesium (chapter 2 title page). Vitamins are also taught (chapter 3, title page) as well as harvested feeds for horses (chapter 4, title page). Sick horse feeding and nutritional support is taught which includes a section on **tube feeding** horses, horses with intestinal disorders, renal failure and hepatic dysfunction (chapter 17, title page). The horse with diarrhea can be feed by stomach tube (page 408, diarrhea). Microorganisms from yogurt or commercial inoculants can be administered (page 408, right column). Vitamin supplement for *renal failure* is recommended (page 413, left

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column). The composition has an effective proportion of components in the absence of evidence to the contrary.

Parsons teaches care and management of the older horse and adding a variety of supplements to the diet of the horse such as nutraceuticals such as chondroitin sulfate and glucosamine(which renders obvious other glucosamine derivatives) (title page, 88 and 89).

Parsons teaches carbohydrates such as glucose and galactose as **monosaccharides** as energy supplying nutrients (Figure 1-3, page 10 of 10). Parsons teaches adding probiotics to horses with diarrhea and to avoid extra fat if the diarrhea is associated with liver disease (pages 210 and 211). Electrolytes can be administered by **stomach tube** (page 211). In liver disease, the vet may insist on **tube feeding** (page 235). A good quality vitamin supplement is recommended and fats and oils are to be kept to a minimum (page 237). In fact, Parsons teaches not to supplement your horse's normal feed with additional fat or oil but to **maintain adequate protein levels** and high in carbohydrates (page 236 to top of page 237). Carbohydrates include glucose and galactose monosaccharides as discussed above. The composition has an effective proportion of components in the absence of evidence to the contrary. Micronized materials are taught (page 237).

Weese et al. teach oral administration of lactase to a lactose intolerant foal (Abstract; J. Am Vet. Med. Assoc 1999, 214(2), 229-32). Thus, the concept of administration of lactase to lactose intolerant equines is established in the art.

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

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1. The difference between the instant application and Lewis is that Lewis do not expressly teach adding between about 1 to 5 wt% lactase or that the whey powder is smaller than about 45 mesh to a composition that is liquid or powder form in a method for reducing energy deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition. This deficiency in Lewis is cured by common sense and the teachings of Weese et al.

2. The difference between the instant application and Lewis is that Lewis do not expressly teach adding the nutrient component, feed component, amino acid chelate, trace mineral, monosaccharides, amino acids, and functional food component as instantly claimed to a human, dog, cow, pig, goat or sheep in a method for reducing energy deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition. This deficiency in Lewis is cured by common sense and the teachings Parsons and Lewis (Equine Clinical Nutrition).

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add between about 1 to 5 wt% lactase, as suggested by common sense and Weese et al., to the composition of Lewis in liquid or powder form, or that the whey powder is smaller than about 45 mesh in a method for reducing energy deficit in a mammal with an energy

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deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the textbook of Lewis clearly teaches that older horses lack lactase and a whey protein supplement rich in lactose can cause diarrhea. The artisan would add lactase to the composition to avoid causing diarrhea in the horse which can lead to dehydration and possibly death. Therefore, in order to avoid diarrhea it is common sense to add lactase to the diet as such a concept is already established by Weese et al. Regarding the amount of lactase, liquid or powder dosage form and the size of the whey powder, the amount of a specific ingredient in a composition, the dosage form of the composition and the size of particular ingredient are clearly a result effective parameters that a person of ordinary skill in the art would routinely optimize or can judiciously select. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. The expected and predictable result is reducing the energy deficit of the horse.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the nutrient component, feed component, amino acid chelate, trace mineral, monosaccharides, amino acids, liquid vitamin and functional food component as instantly claimed to a human, dog, cow, pig, goat or sheep, as suggested by the textbook of Lewis (Equine Clinical Nutrition), Parsons and common sense, in a method for reducing energy

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deficit in a mammal with an energy deficit due to hepatic dysfunction, renal dysfunction or digestive tract condition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art directs one to add these components to treat sick horses. As taught by Lewis (Equine Clinical Nutrition), all the amino acids are contained in the protein supplements. The expected result remains decreasing the energy deficit in the horse. It is known by the references that such compositions decrease the energy deficit, hence provide energy and would be expected to work in any mammal capable of digesting the product. Furthermore, it is merely judicious selection of an amino acid chelate or liquid vitamin in the absence of evidence to the contrary. Applicant has not invented amino acid chelates. A vitamin dissolved in solution would be a liquid vitamin. The expected and predictable result is reducing the energy deficit of the horse.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Summary:**

Equine clinical nutrition, feeding and care are well known in the art of equine care. Textbooks have been written for the artisan on the subject. Providing lactase to lactose intolerant equines is also known in the art of equine care. Therefore, supplementing an equine in need of

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supplementation due to digestive tract conditions, hepatic dysfunction and renal dysfunction to reduce the energy deficit in the equine with whey protein and lactase is obvious to the ordinary artisan in view of the cited references.

**Response to Arguments:**

Applicant's arguments are moot in view of the new ground of rejection.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

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Primary Examiner, Art Unit 1616